

Comparing FDA and ICH (E6) GCP Guidelines

The FDA regulations and ICH GCP guidelines differ on several IRB-related requirements. We have highlighted key differences, but please note that this is not a complete list.

- **Expedited Initial Review of Research:** The FDA allows for IRBs to review certain types of research that do not involve more than minimal risk; ICH GCP Guidelines do not allow expedited Initial review of research.
- **Signature of Person Conducting the Consent Interview:** ICH GCP Guidelines require that the person conducting the consent interview sign and date the informed consent document; the FDA has no such provision.
- **Review of Investigator Qualifications:** ICH GCP Guidelines require that IRBs review the qualifications of the investigator, including the curriculum vitae of the investigator. Although the FDA regulations do not specifically require the review of investigator qualifications, IRBs request site documentation to ensure the requirements of 21 CFR 56.111 are met.
- **Review of Subject Recruitment Procedures:** ICH GCP Guidelines specifically require the IRB to review subject recruitment procedures as well as payments and compensation to study subjects and the investigator's brochure. The FDA regulations only require that IRBs review "all research activities" which are understood to include these elements as well.
- **Copies of Board Roster:** ICH GCP guidelines allow sponsors, investigators and regulatory authorities to request the board roster of the IRB, while the FDA regulations only require that the IRB make this information available to regulatory authorities upon request.

INSIDE THIS ISSUE

Comparing FDA and ICH (E6) GCP Guidelines	1
Harrison IRB Q&A - The Informed Consent Interview	1
Harrison IRB Accreditation Status	1

Harrison IRB Q&A

Question: Who should be present when the informed consent interview is conducted?

Answer: FDA does not require a third person to witness the consent interview unless the subject or representative is not given the opportunity to read the consent document before it is signed. [21 CFR 50.27(b)]. The person who conducts the consent interview should be knowledgeable about the study and able to answer questions*.

[FDA Information Sheet Guidances – Frequently Asked Questions (Informed Consent Process)]

*Please note that Harrison IRB requires that if the person conducting the interview is providing the study information in a language that is understandable to the subject, that person must also be able to answer any questions the potential subject has in the language understandable by him or her.

Harrison IRB Accreditation Status

In July, Harrison IRB attended the AAHRPP Accreditation Workshop in Washington DC.

Harrison IRB has been committed to pursuing accreditation from the inception of the company and continues to strive for excellence by dedicating resources to the accreditation project. A team of staff were identified to lead the accreditation process and we are optimistic that our submission will be completed by the end of 2008. Harrison IRB will continue to provide updates regarding the status of the process and welcome you to contact us for additional information about our accreditation status.